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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,809	09/15/2003	Magnus Hook	P07741US01/BAS	7385

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EXAMINER	
GRASER, JENNIFER E	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
10/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/661,809	HOOK ET AL.	
	Examiner	Art Unit	
	Jennifer E. Graser	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10-13 and 15-41* is/are pending in the application.

4a) Of the above claim(s) *1-8,10-13,15-18,27 and 29-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-26,28 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/14/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.1141.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/19/08 has been entered.

Claims 19-26, 28 and 41 are currently under examination.

Claims 1-8, 10-13, 15-18, 27 and 29-40 were previously withdrawn from consideration.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 19-26, 28 and 41 are rejected under 35 U.S.C. 102(e) as being anticipated by Choi et al (US 6,448,043 B1).

Choi et al teach an isolated protein from *Enterococcus faecalis* (EF040 polypeptide #109) which has an amino acid sequence which is 100% identical to the amino acid sequence set forth in Applicants' SEQ ID NO: 13. See sequence alignment available in public PAIR. Choi teaches polyclonal and monoclonal antibodies which bind this protein and the use of the antibodies as reagents in diagnostic kits and as pharmaceutical compositions for the passive immunization against *E.faecalis*. See the paragraph bridging columns 3-4, column 22; column 23, lines 39-67; column 24line 64-column 25, line 67; kits column 30, lines 19-56; and pharmaceutical compositions/methods of passive immunization column 33 line 10-column 34, line 67.

4. Claims 9, 19-26, 28 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Choi et al (WO 9850554-A2).

Choi et al teach an isolated protein from *Enterococcus faecalis* (EF040 polypeptide #109) which has an amino acid sequence which is 100% identical to the amino acid sequence set forth in Applicants' SEQ ID NO: 13. See sequence alignment

available in public PAIR. Choi teaches polyclonal and monoclonal antibodies which bind this protein and the use of the antibodies as reagents in diagnostic kits and as pharmaceutical compositions for the passive immunization against *E.faecalis*. The disclosure is identical to that contained in US Patent No. 6,448043 above. See the paragraph bridging columns 3-4, column 22; column 23, lines 39-67; column 24 line 64-column 25, line 67; kits column 30, lines 19-56; and pharmaceutical compositions/methods of passive immunization column 33 line 10-column 34, line 67 of that US patent.

5. Claims 19-26, 28 and 41 are rejected under 35 U.S.C. 102(e) as being anticipated by Doucette-Stamm et al (US 6,617,156 B1).

Doucette-Stamm et al teach an isolated protein from *Enterococcus faecalis* (SEQ ID NO: 6124) which has an amino acid sequence which is 100% identical to the amino acid sequence set forth in Applicants' SEQ ID NO: 13. See sequence alignment available in public PAIR. Doucette-Stamm et al teach polyclonal and monoclonal antibodies which bind this protein and the use of the antibodies as reagents in diagnostic kits and as pharmaceutical compositions for the passive immunization against *E.faecalis*. See column 9, line 7-bottom of column 10; column 40, line 23—top of column 42.

Response to Applicants' Arguments:

Applicants argue that all of the cited references, including the Choi references and the Doucette-Stamm patent, are merely "paper patents", i.e., they reflect the sequencing of large amounts of the bacterial genome, and such sequencing and the

projection of possible proteins was done solely through a series of computer algorithms. As a result, there is not a single protein reflected in these references which was actually expressed and/or tested with regard to any characteristics, such as antigenicity. Accordingly, these patents are totally silent as to whether any of the purported polypeptides could even be expressed, whether the expressed product would be stable, or whether the expressed product would be immunogenic, and thus no information is provided which would indicate anything about any of the properties of the predicted proteins and polypeptides in these references, much less any information about whether any antibodies could be generated thereby. Even further, there is no disclosure or suggestion of any specific regions within the purported polypeptides, and thus there is no disclosure of any A domains of any polypeptides, much less any disclosure of any antibody that could bind to the A domains.

These argument have been fully and carefully considered but are not deemed persuasive. Choi et al teach an isolated protein from *Enterococcus faecalis* (EF040 polypeptide #109) which has an amino acid sequence which is 100% identical to the amino acid sequence set forth in Applicants' SEQ ID NO: 13. See sequence alignment available in public PAIR. Choi teaches polyclonal and monoclonal antibodies which bind this protein and the use of the antibodies as reagents in diagnostic kits and as pharmaceutical compositions for the passive immunization against *E.faecalis*. The disclosure is identical to that contained in US Patent No. 6,448043 above. See the paragraph bridging columns 3-4, column 22; column 23, lines 39-67; column 24 line 64-column 25, line 67; kits column 30, lines 19-56; and pharmaceutical

compositions/methods of passive immunization column 33 line 10-column 34, line 67 of that US patent. The reference teaches how to recombinantly produce the proteins. Doucette-Stamm et al teach an isolated protein from *Enterococcus faecalis* (SEQ ID NO: 6124) which has an amino acid sequence which is 100% identical to the amino acid sequence set forth in Applicants' SEQ ID NO: 13. See sequence alignment available in public PAIR. Doucette-Stamm et al teach polyclonal and monoclonal antibodies which bind this protein and the use of the antibodies as reagents in diagnostic kits and as pharmaceutical compositions for the passive immunization against *E.faecalis*. See column 9, line 7-bottom of column 10; column 40, line 23—top of column 42.

All of the cited references specifically teach methods to produce the polypeptides which possess the identical amino acid sequence to Applicants' SEQ ID NO: 13 and a method to produce antibodies which specifically bind thereto. Accordingly, they are anticipatory on the claims. Additionally, Applicants' own method is a 'bioinformatic method to identify and isolate proteins' as well. Applicants' arguments with respect to there is no disclosure of any A domains of any polypeptides, much less any disclosure of any antibody that could bind to the A domains is not commensurate in scope with the claims. The claims recite 'an isolated antibody capable of binding the sequence of amino acids 33-592 of SEQ ID NO: 13'. The polypeptides taught by the prior art references are 100% identical to SEQ ID NO: 13, also 627 amino acids length, e.g., a perfect match. The antibodies generated against these proteins would be identical. Additionally, the antibodies taught by the cited references would inherently possess the capability of binding to amino acids 33-592 of SEQ ID NO: 13, e.g., the polypeptide

minus the signal sequence. An antibody generated from the polypeptide set forth in the amino acid sequence of SEQ ID NO:13 would inherently bind an epitope located within those amino acid sequences.

Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 8:00 AM-6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

/Jennifer E. Graser/
Primary Examiner, Art Unit 1645

10/8/08